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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ- RCRA-2007-0932, FRL-9675-01-OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; **Management Standards for Hazardous Waste Pharmaceuticals (Renewal)**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Management Standards for Hazardous Waste Pharmaceuticals (EPA ICR Number 2486.03, OMB Control Number 2050-0212) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through May 31, 2022. Public comments were previously requested via the *Federal Register* on October 12, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ- RCRA-2007-0932, online using www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2821T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Kristin Fitzgerald, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202-566-0512; email address: fitzgerald.kristin@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov. For further information and updates on EPA Docket Center services, please visit us online at https://www.epa.gov/dockets. The telephone number for the Docket Center is 202-566-1744.

Abstract: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. In 2019 EPA promulgated regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors (84 FR 5816, February 22, 2019). Healthcare facilities (for both humans and animals) and reverse distributors now manage their hazardous waste pharmaceuticals under a new set of sector-specific standards in lieu of the existing hazardous waste generator regulations. These regulations are found in 40 CFR 266, subpart P, and are mandatory. The new requirements include labeling containers holding non-creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals with the words “Hazardous Waste Pharmaceuticals”. Healthcare facilities and reverse distributors must also track or manage rejected shipments by sending a copy of the manifest to the designated facility that returned or rejected the shipment. Additionally, healthcare facilities and reverse distributors must submit exception reports for a missing copy of a manifest. Reverse distributors are required to amend their contingency plan under 40 CFR 262 subpart M. A reverse distributor must submit an unauthorized hazardous

waste report if it receives waste it is not authorized to receive.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are the private sector.

Respondent's obligation to respond: Mandatory (RCRA Section 3001)

Estimated number of respondents: 8,163

Frequency of response: Annual

Total estimated burden: 40,045 hours per year. Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: $3,580,140 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 3,532 hours compared to the currently approved ICR due to a decrease in the universe. The universe estimates are based on real data for this renewal.

Courtney Kerwin,

Director, Regulatory Support Division.

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